



1fw

ATTORNEY DOCKET NO. 07082.0016U1
PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of)	
)	
BALDWIN, et al.)	Art Unit: unassigned
)	
Application No. 10/552,381)	Examiner: unassigned
)	
International Filing Date: April 8, 2004)	Confirmation No. 4746
)	
For: METHOD OF TREATMENT)	
)	

INFORMATION DISCLOSURE STATEMENT

Mail Stop PCT
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

NEEDLE & ROSENBERG, P.C.
Customer Number 23859

Sir:

Pursuant to the requirements of 37 C.F.R. § 1.56, submitted herewith on the accompanying Information Disclosure Statement List is a listing of documents known to Applicants and/or their attorneys. In accordance with 37 C.F.R. § 1.98(a)(2), copies of any cited U.S. patent or U.S. patent application publication documents are not enclosed. Copies of any cited foreign patent document and/or any non-patent publication are enclosed.

This Information Disclosure Statement is believed to be filed in a timely manner pursuant to 37 C.F.R. § 1.97(b)(3), in that a first Office Action on the merits of the present patent application has not yet been mailed to Applicants.

Consideration of the cited documents and making the same of record in the prosecution of the above-referenced application are respectfully requested.

ATTORNEY DOCKET NO. 07082.0016U1

Application No. 10/552,381

No fee is believed to be due; however, the Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 14-0629.

Respectfully submitted,

NEEDLE & ROSENBERG, P.C.



Gwendolyn D. Spratt
Registration No. 36,016

NEEDLE & ROSENBERG, P.C.
Customer Number 23859
(678) 420-9300
(678) 420-9301 (fax)

CERTIFICATE OF MAILING UNDER 37 C.F.R. § 1.8

I hereby certify that this correspondence, including any items indicated as attached or included, is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Mail Stop PCT, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on the date indicated below.



Gwendolyn D. Spratt

10-10-06

Date



INFORMATION DISCLOSURE STATEMENT LIST		Complete if Known	
		Application Number	10/552,381
(Use as many sheets as necessary)		International Filing Date	April 8, 2004
		First Named Inventor	BALDWIN, et al.
		Group Art Unit	Unassigned
		Examiner Name	unassigned
NON-PATENT DOCUMENTS			
Examiner's Initials	Cite No.	Non-Patent Citations (include Author, Title, Publisher, Relevant Pages, Date and Place of Publication)	
	A5	Baldwin, G.S. The role of gastrin and cholecystokinin in normal and neoplastic gastrointestinal growth. J. Gastro. Hepatol. 10, 215-232(1995).	
	A6	Baldwin, G.S. Comparison of sequences of the 78 kDa gastrin-binding protein and some enzymes involved in fatty acid oxidation. Comp. Biochem. Physiol. 104B:55-61(1993).	
	A7	Baldwin, G.S., Hollande, F., Yang, Z., Karelina, Y., Paterson, A., Strang, R., Fourmy, D., Neumann, G. and Shulkes, A. Biologically active recombinant human progastrin ₆₋₈₀ contains a tightly bound calcium ion. J. Biol. Chem. 276: 7791-7796 (2001).	
	A8	Baldwin GS, Curtain CC, Sawyer WH. Selective, high-affinity binding of ferric ions by glycine-extended gastrin(17). Biochemistry; 40:10741-10746 (2001).	
	A9	Baldwin GS and Shulkes A. Gastrin, gastrin receptors and colorectal carcinoma. Gut. 42:581-584(1998).	
	A10	Barnham, K.J., Torres, A.T., Alewood, D., Alewood, P.F., Domagala, T., Nice, E.C., & Norton, R.S. Protein Sci. 7, 1738-1749(1998).	
	A11	Barnham KJ, Catalfamo F, Pallaghy PK, Howlett GJ, Norton RS. Helical structure and self association in a 13 residue neuropeptide YY2 receptor agonist: relationship to biological activity. Biochem. Biophys. Acta. 1435:127-137 (1999).	
	A12	Bower, J.M. et al. Trypsinogen Activation Peptide and Related Peptides as inhibitors of Gastric Secretion. Biochemical and Biophysical Research Communications (1974) Vol. 60, No. 2, pages 820-824.	
	A13	Chemical Abstracts, Accession No. 82:125591. Penke, B. et al. Peptide syntheses. LVIII. Suppression of deletion sequences by 3-nitrophthalic anhydride. Merrifield syntheses of leucine 5 – gastrin I sequence 5-12 and ACTH fragment 11-14. Justus Liebig's Annalen der Chemie, 1975, No. 12, pages 1999-2002.	
	A14	Chen D, Zhao CM, Dockray GJ, Varro A, Van Hoek A, Sinclair NF, Wang TC, Koh TJ. Glycine-extended gastrin synergizes with gastrin 17 to stimulate acid secretion in gastrin-deficient mice. Gastroenterology. 119:756-65 (2000).	
	A15	Cobb S, Wood T, Tessarollo L, Velasco M, Given R, Varro A, et al. Deletion of functional gastrin gene markedly increases colon carcinogenesis in response to azoxymethane in mice. Gastroenterology 123:516-530 (2002).	
Examiner Signature:		Date Considered:	
EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.			



INFORMATION DISCLOSURE STATEMENT LIST		Complete if Known	
		Application Number	10/552,381
(Use as many sheets as necessary)		International Filing Date	April 8, 2004
		First Named Inventor	BALDWIN, et al.
		Group Art Unit	Unassigned
		Examiner Name	unassigned
NON-PATENT DOCUMENTS			
Examiner's Initials	Cite No.	Non-Patent Citations (include Author, Title, Publisher, Relevant Pages, Date and Place of Publication)	
	A16	Cui H, Cruz-Correa M, Giardiello FM, Hutcheon DF, Kafonek DR, Brandenburg S, Wu Y, He X, Powe NR, Feinberg AP. Loss of IGF2 Imprinting: A Potential Marker of Colorectal Cancer Risk. Science 299:1753-1755 (2003).	
	A17	De Hauwer, C., Camby, I., Darro, F., Migeotte, I., Decaestecker, C., Verbeek, C., Danguy, A., Pasteels, J.L., Brotchi, J., Salmon, I., Van Ham, P., and Kiss, R. J. Neurobiol. 37, 373-382 (1998).	
	A18	Dockray, GJ. Gastrin and gastric epithelial physiology J. Physiol. 518:315-324 (1999).	
	A19	Galleyrand JC, Lima-Leite AC, Lallement JC, Lignon MF, Bernad N, Fulcrand P, Martinez J. Synthesis and characterization of a new labeled gastrin ligand, 125-I-BH-[Leu15]-gastrin-(5-17), on binding to canine fundic mucosal cells and Jurkat cells. Int J Pept Protein Res. 44:348-356 (1994).	
	A20	Gorbach SL. Bismuth therapy in gastrointestinal diseases. Gastroenterology 99:863-875 (1990).	
	A21	Gregory, R.A. et al. Minigastrin: Corrected Structure and Synthesis. Hoppe-Seyler's Z. Physiol. Chem. (1979), Vol. 360 No. 1, pages 73-80.	
	A22	Hann HW, Stahlhut MW, Rubin R, Maddrey WC. Antitumor effect of deferroxamine on human hepatocellular carcinoma growing in athymic nude mice. Cancer 70:2051-2056 (1992).	
	A23	Henwood M, Clarke PA, Smith AM, Watson SA. Expression of gastrin in developing gastric adenocarcinoma. Br J Surg 88:564-568 (2001).	
	A24	Higashide S, Gomez G, Greeley GH Jr, Townsend JC. Glycine-extended gastrin potentiates gastrin-stimulated gastric secretion in rats. Am. J. Physiol. 270(1 Pt1):G220-G224 (1996).	
	A25	Hirata M, Itoh M, Tsuchida A, Ooishi H, Hanada K, Kajiyama G. Cholecystokinin receptor antagonist, loxiglumide, inhibits invasiveness of human pancreatic cancer cell lines. FEBS Lett 383:241-244 (1996).	
	A26	Hollande F, Blanc EM, Bali JP, Whitehead RH, Pelegri A, Baldwin GS, Choquet A. HGF regulates tight junctions in new nontumorigenic gastric epithelial cell line. Am. J. Physiol. 280:G910-G921 (2001).	
	A27	Hollande F, Choquet A, Blanc EM, Lee DJ, Bali JP, Baldwin GS. Involvement of phosphatidylinositol 3-kinase and mitogen-activated protein kinases in glycine-extended gastrin-induced dissociation and migration of gastric epithelial cells. J. Biol. Chem. 276:40402-40410 (2001).	
	A28	Hollande F, Imdahl A, Mantamadiotis T, Ciccotosto GD, Shulkes A, Baldwin GS. Glycine-extended gastrin acts as an autocrine factor in a nontransformed colon cell line. Gastroenterology. 113:1576-1588 (1997).	
Examiner Signature:		Date Considered:	
EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.			



INFORMATION DISCLOSURE STATEMENT LIST		Complete if Known	
		Application Number	10/552,381
(Use as many sheets as necessary)		International Filing Date	April 8, 2004
		First Named Inventor	BALDWIN, et al.
		Group Art Unit	Unassigned
		Examiner Name	unassigned
NON-PATENT DOCUMENTS			
Examiner's Initials	Cite No.	Non-Patent Citations (include Author, Title, Publisher, Relevant Pages, Date and Place of Publication)	
	A29	Ito, M., Matsui, T., Taniguchi, T., Tsukamoto, T., Murayama, T., Arima, N., Nakata, H., Chiba, T., & Chihara, K. J. Biol. Chem. 268, 18300-18305 (1993).	
	A30	Iwase K, Evers BM, Hellmich MR, Guo YS, Higashide S, Kim HJ et al. Regulation of growth of human gastric cancer by gastrin and glycine-extended progastrin. Gastroenterology 113:782-790 (1997).	
	A31	Kaise, M., Muraoka, A., Seva, C., Takeda, H., Dickinson, C.J., & Yamada, T. J. Biol. Chem. 270, 11155-11160 (1995).	
	A32	Kermorgant S, Lehy T. Glycine-extended gastrin promotes the invasiveness of human colon cancer cells. Biochem. Biophys. Res. Commun. 285:136-141 (2001).	
	A33	Kicic A, Chua AC, Baker E. Effect of iron chelators on proliferation and iron uptake in hepatoma cells. Cancer 92:3093-3110 (2001).	
	A34	Kidd M, Modlin I, Tang L. Gastrin and the enterochromaffin like cell: an update. Dig Surg 15:209-217 (1998).	
	A35	Kirtan CM, Wang T, Dockray GJ. Regulation of parietal cell migration by gastrin in the mouse. Am. J. Physiol. 283:G787-G793 (2002).	
	A36	Kneib-Cordonier et al. Orthogonal solid-phase synthesis of human gastrin-I under mild conditions. International Journal of Peptide and Protein Research (1990, Vol. 35, No. 6, pages 527-538).	
	A37	Koh TJ, Dockray GJ, Varro A, Cahill RJ, Dangler CA, Fox JG, Wang TC. Overexpression of glycine-extended gastrin in transgenic mice results in increased colonic proliferation. J. Clin. Invest. 103:1119-1126 (1999).	
	A38	Koh, T.J., Bulitta, C.J., Fleming, J.V., Dockray, G.J., Varro, A. and Wang, T.C. Gastrin is a target of the β -catenin/TCF-4 growth-signaling pathway in a model of intestinal polyposis. J. Clin. Invest. 106: 533-539 (2000).	
	A39	Kopin, A.S., Lee, Y.M., Mc Bride, E.W., Miller, L.J., Kolakowski, L.F., & Beinborn, M. Proc. Natl. Acad. Sci. U. S. A. 89, 3605-3610 (1992).	
	A40	Koradi, R., Billeter, M., & Wütrich, R. J. Mol. Graph. 14, 51-55 (1996).	
	A41	Lehy T. Trophic effect of some regulatory peptides on gastric exocrine and endocrine cell of the rat. Scand J Gastroenterol 19(Suppl 101):27-30 (1984).	
Examiner Signature:		Date Considered:	
EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.			



INFORMATION DISCLOSURE STATEMENT LIST		Complete if Known	
		Application Number	10/552,381
(Use as many sheets as necessary)		International Filing Date	April 8, 2004
		First Named Inventor	BALDWIN, et al.
		Group Art Unit	Unassigned
		Examiner Name	unassigned
NON-PATENT DOCUMENTS			
Examiner's Initials	Cite No.	Non-Patent Citations (include Author, Title, Publisher, Relevant Pages, Date and Place of Publication)	
	A42	Linse S, Johansson C, Brodin P, Grundstrom T, Drakenberg T, Forsen S. Electrostatic contributions to the binding of Ca^{2+} in calbindin D_{9k} . Biochemistry. 30:154-162 (1991).	
	A43	Litvak DA, Hellmich MR, Iwase K, Evers BM, Martinez J, Amblard M et al. JMV1155: a novel inhibitor of glycine-extended progastrin-mediated growth of a human colon cancer in vivo. Anticancer Res 19:45-9 (1999).	
	A44	Malby S, Pickering R, Saha S, Smallridge R, Linse S, Downing AK. The first epidermal growth factor-like domain of the low-density lipoprotein receptor contains a noncanonical calcium binding site. Biochemistry 40:2555-2563 (2001).	
	A45	Marshall BJ, Armstrong JA, Francis GJ, Mokes NT, Wee SH. Antibacterial action of bismuth in relation to Campylobacter pyloridis colonization and gastritis. Digestion. 37 (Suppl 2):16-30 (1987).	
	A46	McLellan, E.A. & Bird, R.P. Specificity study to evaluate induction of aberrant crypts in murine colons. Cancer Res. 48: 6183-6186 (1988).	
	A47	Moore, C., Jie, R., Shulkes, A., & Baldwin, G.S. DNA Sequence. 8, 39-44 (1997).	
	A48	Morley JS, Tracy HJ & Gregory RA. Structure-function relationships in the active C-terminal tetrapeptide sequence of gastrin. Nature 207:1356-1359 (1965).	
	A49	Moser, A.R., Pitot, H.C. & Dove, W.F. A dominant mutation that predisposes to multiple intestinal neoplasia in the mouse. Science. 247: 322-324 (1990).	
	A50	Okada N, Kubota A, Imamura T, Suwa H, Kawaguchi Y, Ohshio G et al. Evaluation of cholecystokinin, gastrin, CCK-1 receptor, and CCK-2/gastrin receptor gene expressions in gastric cancer. Cancer Lett 106:257-262 (1996).	
	A51	Palumbo, M., Jaeger, E., Knof, S., Peggion, E., & Wunsch E. FEBS Lett. 119, 158-161 (1980).	
	A52	Pannequin, et al. Ferric Ions are essential for the Biological Activity of the Hormone Glycine-extended Gastrin. Journal of Biological Chemistry, 2002, vol. 277, No. 50, pages 48602-48609.	
	A53	Qian JM, Rowley WH, Jensen RT. Gastrin and CCK activate phospholipase C and stimulate pepsinogen release by interacting with two distinct receptors. Am. J. Physiol. 264:G718-G727 (1993).	
Examiner Signature:		Date Considered:	
EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.			



INFORMATION DISCLOSURE STATEMENT LIST		Complete if Known	
		Application Number	10/552,381
(Use as many sheets as necessary)		International Filing Date	April 8, 2004
		First Named Inventor	BALDWIN, et al.
		Group Art Unit	Unassigned
		Examiner Name	unassigned
NON-PATENT DOCUMENTS			
Examiner's Initials	Cite No.	Non-Patent Citations (include Author, Title, Publisher, Relevant Pages, Date and Place of Publication)	
	A54	Reubi JC, Waser B, Schmassmann A, Laissue JA. Receptor autoradiographic evaluation of cholecystikinin, neurotensin, somatostatin and vasoactive intestinal peptide receptors in gastro-intestinal adenocarcinoma samples: where are they really located? Int J Cancer 81:376-386 (1999).	
	A55	Rooman I, Lardon J, Flamez D, Schuit F, Bouwens L. Mitogenic effect of gastrin and expression of gastrin receptors in duct-like cells of rat pancreas. Gastroenterology 121:940-949 (2001).	
	A56	Seet L, Fabri L, Nice EC, Baldwin GS. Comparison of iodinated [Nle15]- and [Met15]-gastrin17 prepared by reversed-phase HPLC. Biomed. Chromatogr. 2:159-163 (1987).	
	A57	Seimann. In: Rodent Tumor Models in Experimental Cancer Therapy Ed. Kallman. pp. 12-15. (Pergamon Press, N.Y.) (1987)	
	A58	Selig RA, White L, Gramacho C, Sterling-Levis K, Fraser IW, Naidoo D. Failure of iron chelators to reduce tumor growth in human neuroblast xenografts. Cancer Res. 58:473-8 (1998).	
	A59	Seva C, Dickinson CJ, Yamada T. Growth-promoting effects of glycine - extended progastrin. Science 265:410-412 (1994).	
	A60	Singh P, Velasco M, Given R, Wargovich M, Varro A, Wang TC. Mice overexpressing progastrin are predisposed for developing aberrant colonic crypt foci in response to AOM. Am. J. Physiol. 278:G390-G399 (2000a).	
	A61	Singh P, Velasco M, Given R, Varro A, Wang TC. Progastrin expression predisposes mice to colon carcinomas and adenomas in response to a chemical carcinogen. Gastroenterology 119:162-171 (2000b).	
	A62	Stepan VM, Sawada M, Todisco A, Dickinson CJ. Glycine-extended gastrin exerts growth-promoting effects on human colon cancer cells. Mol Med. 5:147-59 (1999).	
	A63	Torda, A.E., Baldwin, G.S., & Norton, R.S. Biochem. 24, 1720-1727 (1985).	
	A64	Tracy HJ and Gregory RA. Physiological properties of a series of synthetic peptides structurally related to gastrin I. Nature 204:935 (1964).	
	A65	Van Oijen AHAM, Verbeek AL, Jansen JBMJ, De Boer WA. Treatment of Helicobacter pylori infection with ranitidine bismuth citrate- or proton pump inhibitor-based triple therapies. Aliment Pharmacol Ther 14:991-999 (2000).	
Examiner Signature:		Date Considered:	
EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.			



INFORMATION DISCLOSURE STATEMENT LIST		Complete if Known	
		Application Number	10/552,381
(Use as many sheets as necessary)		International Filing Date	April 8, 2004
		First Named Inventor	BALDWIN, et al.
		Group Art Unit	Unassigned
		Examiner Name	unassigned
NON-PATENT DOCUMENTS			
Examiner's Initials	Cite No.	Non-Patent Citations (include Author, Title, Publisher, Relevant Pages, Date and Place of Publication)	
	A66	Waldum HL, Qvigstad G, Marvik R, Brenna E, Syversen U, Sandvik AK The effect of tripotassium dicitrato bismuthate on the rat stomach. Aliment Pharmacol Ther 8:425-431 (1994).	
	A67	Wang TC, Koh TJ, Varro A, Cahill RJ, Dangler CA, Fox JG, Dockray GJ. Processing and proliferative effects of human progastrin in transgenic mice. J Clin Invest. 98:1918-1929 (1996).	
	A68	Weinstock J and Baldwin GS. Binding of gastrin ₁₇ to human gastric carcinoma cell lines. Cancer Res. 48:932-937 (1988).	
	A69	Wieriks J, Hespe W, Jaitly KD, Koekkoek PH, Lavy U Pharmacological properties of colloidal bismuth subcitrate. Scand J Gastroenterol 17 (Suppl 80):11-16 (1982).	
	A70	Winzor DJ and Sawyer WH. Quantitative Characterisation of Ligand Binding, pp. 28-41, Wiley-Liss, New York (1995).	
	A71	Wroblewski, L.E., Pritchard, D.M., Carter, S., and Varro, A. Biochem. J. 365: 873-879 (2002).	
	A72	Yang CH, Ford J, Karelina Y, Shulkes A, Xiao SD, Baldwin GS. Identification of a 70-kDa gastrin-binding protein on DLD-1 human colorectal carcinoma cells. Int. J. Biochem. Cell Biol. 33:1071-1079 (2001).	
Examiner Signature:		Date Considered:	
EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.			